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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,531	03/15/2004	Samuel Achilefu	MRD-64CP (1448.2 US)	2309
27805	7590	01/04/2008	EXAMINER	
THOMPSON HINE L.L.P.			JONES, DAMERON LEVEST	
Intellectual Property Group				
P.O. BOX 8801			ART UNIT	PAPER NUMBER
DAYTON, OH 45401-8801			1618	
			MAIL DATE	DELIVERY MODE
			01/04/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/800,531	ACHILEFU ET AL.	
	Examiner	Art Unit	
	D. L. Jones	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/23/07.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 10/23/07 wherein claims 1-31 and 36-44 were canceled and claims 32 and 35 were amended.

Note: Claims 32-35 are pending.

RESPONSE TO APPLICANT'S ARGUMENTS/AMENDMENT

2. The Applicant's arguments and/or amendment filed 10/23/07 to the rejection of claims 32-35 made by the Examiner under 35 USC 102, 112, and/or double patenting have been fully considered and deemed persuasive-in-part for the reasons set forth below. **Double Patenting Rejections**

I. The rejection of claims 32-35 over US Patent No. 6,706,254 is WITHDRAWN because Applicant has submitted an acceptable terminal disclaimer.

II. The rejection of claims 32-34 on the ground of non-statutory obviousness-type double patenting as being unpatentable over claim 1 of US Patent No. 6,395,257 is MAINTAINED for reasons of record in the office action mailed 7/23/07 and those set forth below.

Applicant asserts that no double patenting exists because the instant invention recites 'a biocompatible organic solvent' wherein the patent recites 'a pharmaceutically acceptable carrier' and a pharmaceutically acceptable carrier need not render organic solvents obvious because of solubility differences.

Applicant's argument is non-persuasive because the term 'pharmaceutically acceptable carrier' would include some 'biocompatible organic solvents' such as dimethylsulfoxide (DMSO) which is being claimed by Applicant. For example, in support

of the Examiner's position that DMSO, listed as one of Applicant's biocompatible organic solvents, may be a pharmaceutically acceptable carrier, Piacquadio (US Patent No. 5,605,684), Westwood et al (US Patent No. 7,067,315), and Gillis et al (US Patent No. 6,989,157) are included with this office action.

Piacquadio discloses thalidomide compositions that are useful for treating surface wounds, inflammatory disorders, ophthalmic mucosal, conjunctiva and other ocular disorders, ulcerations and lesions (see entire document, especially, abstract). In particular, in column 4, lines 34-35, Piacquadio discloses that dimethyl sulfoxide (DMSO) may also be used as a suitable pharmaceutical carrier for the thalidomide compositions that are administered to subjects.

Gillis et al disclose powders of metal containing compounds that are used in treating subjects with various conditions (see entire document, especially, abstract). In particular, in column 10, lines 22-25, Gillis et al disclose that certain musculo-skeletal conditions may be treated by using a pharmaceutical carrier composition of the metal containing material such as a penetrating pharmaceutical carrier composition containing DMSO.

Westwood et al disclose methods for monitoring cell invasion by parasites. In addition, Westwood et al disclose pharmaceutical compositions that have anti-protozoal activity and are useful for treating infections. In column 5, lines 48-52, it is disclosed that that the composition comprises a pharmaceutically acceptable carrier wherein the pharmaceutically acceptable carrier is not dimethylsulfoxide (DMSO). Thus, indicating

that DMSO can be a pharmaceutically acceptable carrier even though it is not the desired carrier in Westwood et al.

Hence, it is the Examiner's position that the double patenting rejection over US Patent No. 6,395,257 is proper.

112 Rejections

The 112, second paragraph, rejections are WITHDRAWN for reasons of record in Applicant's response filed 10/23/07.

102 Rejections

Applicant's arguments with respect to claims 32-35 have been considered but are moot in view of the new ground(s) of rejection. Thus, the 102 (b) and 102(e) rejections are WITHDRAWN.

Applicant asserts that neither Eversole et al nor Licha et al disclose that the concentrations of biocompatible organic solvent enhance dye fluorescence. In addition, Applicant asserts that the claims have been amended to recite that the method is performed in order the enhance dye fluorescence during the photodiagnostic or phototherapeutic procedure.

Applicant's arguments are non-persuasive because if both Applicant and the cited prior art documents disclose a dye in combination with a biocompatible organic solvent as set forth in the instant invention, then a skilled artisan would recognize that the compositions, which are used for fluorescence in the instant invention and the cited prior art, would behave the same since a composition is inseparable from its properties. Thus, if the presence of the organic solvent in Applicant's composition results in

enhanced fluorescence during the photodiagnostic/phototherapeutic procedure, the same enhancement would occur for the cited prior art compositions that are also used for fluorescence purposes. Furthermore, it is noted that for Licha et al, like Applicant, cyanine dyes are used.

NEW GROUNDS OF REJECTIONS

103 Rejections

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 32-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eversole et al (SPIE, 1993, Vol. 1862, pages 209-217).

Eversole et al disclose a study involving microdroplet missing resonance spectroscopy. In addition, Eversole et al disclose fluorescent emission resonances in ethanol droplets (see entire document, especially, page 209, abstract and introduction). In particular, bromo-cresol green dye in combination with rhodamine-6G (R6G) dye and ethanol is disclosed (page 215, 'Discussion', lines 1-3). In Figure 8, the spectra from droplets of three solutions are disclosed. The lower spectrum is an unmixed R6G reference. The upper and middle spectra are from R6G/BCG solutions which are acidified and neutral, respectively.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Eversole et al to encompass the concentration range of biocompatible organic solvent; thus, enhancing fluorescence to the photodiagnostic procedure for the following reasons. Both Applicant and Eversole et al disclose methods which involve compositions comprising a dye and a compatible organic solvent. Eversole et al disclose that the concentration of ethanol (biocompatible organic solvent) can be determined in the composition (page 209, 'Introduction'). In addition, it is noted that Eversole et al disclose that bromo-cresol green dye additive has diagnostic applications. While Eversole et al do not specifically state that fluorescence

was enhanced in the presence of a photodiagnostic procedure, it would have been obvious to one at the time the invention was made that enhance fluorescence occurs because (1) both Applicant and Eversole et al are using a composition comprising the same components (a dye and a biocompatible organic solvent) and Figure 8 of Eversole et al disclose enhanced fluorescence intensity spectra for solutions comprising the acidified and neutralized solutions containing the bromo-cresol green dye-biocompatible organic solvent combination when compared to the solution containing only the dye.

7. Claims 32-35 are rejected under 35 U.S.C. 103(a) as being unpatentable Licha et al (US Patent No. 6,083,485).

Licha et al disclose dyes and methods of using the dyes. The compositions of Licha et al comprise a biological detectable unit (B), a hydrophilic group (W), and a dye (F) (column 4, lines 6-28). Possible dyes useful with the instant invention include, cyanine dyes (columns 4-5, bridging paragraph), squarain dyes (column 6, lines 17-45), styryl dyes (column 6, lines 47-62), and merocyanine dyes (columns 6-7, bridging paragraph). Fluorescence radiation is recorded and an image is generated from the data obtained (column 8, lines 46-61). In the formula $BI-(F-W_m)_n$ (column 9, lines 54-64) the compounds may be added to a n-octanol/Tris buffer. In Example 2 (column 16), a dye composition is disclosed in combination with an organic solvent (isopropanol). Likewise, in Example 7 (column 17), another dye is disclosed in combination with isopropanol. While Licha et al do not specifically state that fluorescence is enhanced when the dye is in the presence of the biocompatible organic solvent, a skilled

practitioner in the art would recognize that since both Applicant and Licha et al disclose dyes in combination with a biocompatible organic solvent (i.e., isopropanol), it would be inherent that in both instances fluorescence. Also, the skilled artisan would recognize that if both Applicant and the prior art disclose the same components, then since a composition is inseparable from its properties, the properties of Applicant's composition (enhanced fluorescence) would also be exhibited by the prior art's composition. Furthermore, since both Applicant and Licha et al disclose methods of performing diagnostic procedures, it would be obvious to the skilled artisan that fluorescence is enhanced.

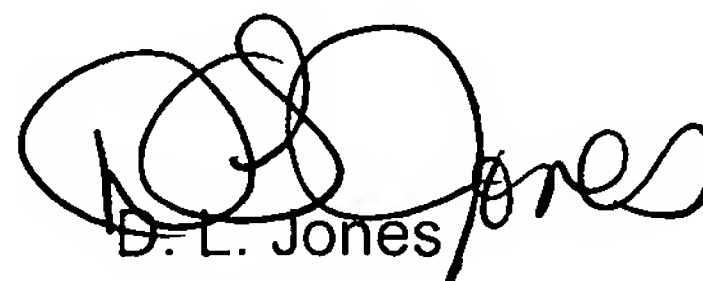
8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


D. L. Jones
Primary Examiner
Art Unit 1618

December 31, 2007